**Remarks**

Claims 48 and 70-71 are pending in this application. Claims 52, 54, 61, and 69 are canceled without prejudice to Applicants' right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications.

Claim 48 is amended to recite, in part, a solid pharmaceutical composition comprising 5 mg of descarboethoxyloratadine ("DCL"), which is suitable for oral administration. The support for the additional limitations can be found, for example, on page 16, lines 1-9 and page 14, lines 11-16 of the specification. Claim 48 is also amended to remove the recitation of "the treatment of allergic rhinitis or urticaria." Claim 71 is amended to correct its dependency. No new matter has been encompassed by these amendments, as discussed in more detail below.

Applicants respectfully submit that all of the pending claims are allowable for at least the following reasons.

A. No New Matter Has Been Added

In the Advisory Action, it is alleged that "[N]o antecedent basis or description for a single 5 mg dosage" is found because the specification "disclosed explicitly ranges of unit dosage as 0.1-10 mg, 0.1-5 mg, or 0.2-1 mg." (Advisory Action, page 2). Applicants respectfully traverse.

The 5 mg dosage cannot constitute a new matter because such is specifically disclosed in the specification at page 14, line 16. Indeed, those of ordinary skill in the art would have recognized that the "5 mg" dosage was expressly and specifically disclosed in the present specification, since the dosage is described in the specification as the end point of "0.1 mg to 5 mg" range. (*See* Specification, page 14, line 16). Clearly, such description would be "blaze marks which single out particular trees," in this case, the 5 mg composition. (*See In re Ruschig*, 379 F.2d 990, 994-5 (C.C.P.A. 1967); *see also Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996)). For this reason, Applicants respectfully submit that the pending claims are adequately supported by the specification as originally filed, and no new matter has been encompassed by the claim amendments made herein.

B. The Rejection Under 35 U.S.C. § 112 Should Be Withdrawn

On page 2 of the Office Action, claim 48 is rejected as allegedly indefinite. In particular, it is alleged that the claims is indefinite based on the Examiner's assertion that

the term "for the treatment of allergic rhinitis and urticaria" fails to further limit the scope of the claim, and is irrelevant.

Although Applicants respectfully disagree, that limitation is removed from claim 48 to expedite the prosecution of this application. Consequently, Applicants respectfully request that the rejection of claim 48 under 35 U.S.C. § 112, ¶2 be withdrawn.

C. The Rejection Under Non-Statutory Double Patenting

On pages 2-3 of the Office Action, claims 48 and 70 are rejected under the judicially-created obviousness type double patenting over claims 48-57 of co-pending application no. 10/989,514 ("the '514 application"). However, the claims currently pending in the '514 application do not recite subject matter which overlaps with that recited by the present application. (*See* Applicants Response of March 15, 2006 in the '514 application, in particular, claim amendments made therein). Specifically, while the claims currently pending in the '514 application recite a method of treatment, the present claims are directed to a composition. In view of this fact, Applicants respectfully request that the rejection under non-statutory double patenting should be withdrawn.

Alternatively, a terminal disclaimer with provision for the required fee is provided herewith. In either case, the rejection should be withdrawn.

D. The Rejection Under 35 U.S.C. § 102 Should Be Withdrawn

On pages 3-4 of the Office Action, claims 48 and 70 are rejected as allegedly anticipated by U.S. Patent No. 4,659,716 to Villani *et al.* ("Villani") for the reasons stated in the Office Action. Applicants respectfully disagree.

It is well-settled that "[a] claim is anticipated only if each and every element as set for the in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully point out that the claims are not anticipated because Villani fails to disclose "each and every element" of the claims.

Claim 48 recites, in part, a solid pharmaceutical composition comprising 5 mg of DCL, which is suitable for oral administration. Villani does not anticipate the claimed composition. Villani discloses a genus of compounds which encompasses DCL, although Applicants note that DCL is disclosed as an example. Furthermore, Villani discloses a very broad range of amount of active ingredient, *i.e.*, 1-1000 mg, that can purportedly be used in compositions. Therefore, Villani discloses a composition containing 1-1000 mg

of DCL.[1] Furthermore, the specific compositions of DCL disclosed in Villani, *i.e.*, those disclosed in Examples E-I of Villani contain: 200mg/g; 200mg/g; 200 mg/g; 200mg/g; and 100 mg/g of DCL, respectively.[2] These amounts are significantly different than the amounts recited by the pending claims.

In view of the broad range and much higher amounts of DCL, the compositions disclosed in Villani are clearly different from a solid pharmaceutical composition comprising 5 mg of DCL, suitable for oral administration. (*See In re Meyer*, 599 F.2d 1026 (C.C.P.A. 1979) (holding that claim to a species is not anticipated by a prior are reference disclosing a genus because the prior art embraced a large number of species); *see also generally*, *In re Peterson*, 315 F.3d 1325 (Fed. Cir. 2003), where a claim to a super-alloy containing about 1-3% rhenium and about 14% chromium was rejected under 35 U.S.C. § 103 over a reference that discloses a similar super-alloy containing 0-7% rhenium and 3-18% chromium, but no rejection under 35 U.S.C. § 102 was made). Consequently, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 102 be withdrawn.

E. The Rejection Under 35 U.S.C. § 103 is Obviated

On pages 4-5 of the Office Action, claims 54 and 61 are rejected as allegedly obvious over Villani in view of Berkow *et al.*, *The Merck Manual of Diagnosis and Therapy*, 16th Ed., pp 326-332 (1992). Although Applicants respectfully disagree, the rejection is obviated in view of the cancellation of claims 54 and 61. Thus, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

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[1] Applicants respectfully point out that Villani even falls short of disclosing such a composition. This is because, while DCL is disclosed as an exemplary compound, Villani makes it clear that its preferred compound is not DCL. *See* Villani, column 11, lines 21-23.

[2] Therefore, in connection with compositions, Villani only discloses a broad range of amount (*i.e.*, 1-1000 mg) and several exemplary compositions containing an amount of DCL much higher than 5 mg. While no description whatsoever of unit dose is provided in Villani, Applicants note that Villani alleges that the compounds it discloses may be administered, for example, in an amount of 10-20 mg per day in two to four divided doses. (*See* Villani, col. 11, lines 24-33). This disclosure may arguably be interpreted to suggest a genus of doses, which may include 5 mg. However, while it may arguably disclose a broader genus, Villani does not disclose, specifically or inherently, a composition comprising specifically 5 mg of DCL. As well-settled, the disclosure of a genus does not anticipate a species. (*See, e.g.*, *In re Meyer*, 599 F.2d 1026 (C.C.P.A. 1979)). Furthermore, when combined with the disclosures of a much broader general range and exemplary compositions containing much higher amount of DCL in connection with compositions, Villani cannot anticipate the presently claimed invention. (*See generally In re Arkley*, 455 F.2d 586 (C.C.P.A. 1972)).

Conclusion

For at least the foregoing reasons, Applicants respectfully submit all of the pending claims are allowable, and thus respectfully request the allowance thereof.

No fee is believed due for this submission. Should any additional fees be required for this submission or to avoid abandonment of the application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date March 17, 2006

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